

# **VFC Resolution Update: Hepatitis B Vaccine**

**Jeanne M. Santoli  
Immunization Services Division  
National Center for Immunization and  
Respiratory Diseases  
February 22, 2017**



**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION**



**SAFER · HEALTHIER · PEOPLE**

# Purpose of the Updated Resolution

- The purpose of this resolution is to clarify recommendations related to dosing intervals and revaccination.

# Eligible Groups

**All children and adolescents birth through 18 years of age.**

# Recommended Schedule and Intervals, I

The tables below list the acceptable vaccination schedules for children and adolescents birth through 18 years of age.

Table 1, Part I: Infants

Birth weight	Maternal HBsAg status	Single antigen vaccine		Single-antigen <sup>1</sup> and combination vaccine <sup>2,3</sup>	
		Dose	Age	Dose	Age
≥2000 g	Positive	1	Birth (≤12 hrs) <sup>1</sup>	1	Birth (≤12 hrs) <sup>1</sup>
		2	1-2 months	2	2 months
		3	6 months	3	4 months
				4	6 months
	Unknown	1	Birth (≤12 hrs) <sup>1</sup>	1	Birth (≤12 hrs) <sup>1</sup>
		2	1-2 months	2	2 months
		3	6 months	3	4 months
				4	6 months
	Negative	1	Birth (≤ 24 hours) <sup>1</sup>	1	Birth (≤ 24 hours) <sup>1</sup>
		2	1-2 months	2	2 months
		3	6 -18 months	3	4 months
				4	6 months

# Recommended Schedule and Intervals, II

Table 1, Part 2: Infants

<2000 g	Positive	1	Birth (< 12 hrs) <sup>1</sup>	1	Birth (< 12 hrs) <sup>1</sup>
		2	1 month	2	2 months
		3	2-3 months	3	4 months
		4	6 months	4	6 months
	Unknown	1	Birth (≤12 hrs) <sup>1</sup>	1	Birth (≤12 hrs) <sup>1</sup>
		2	1 month	2	2 months
		3	2-3 months	3	4 months
		4	6 months	4	6 months
	Negative	1	Age 1 month or at hospital discharge <sup>1</sup>	1	Age 1 months or at hospital discharge <sup>1</sup>
		2	2 months	2	2 months
		3	6 -18 months	3	4 months
				4	6 months

Table Notes:

1. Only a single antigen hepatitis B vaccine (ENGERIX-B® or RECOMBIVAX HB®) can be given at birth.
2. Pediarix® [DTaP-IPV-HepB] is licensed for children 6 weeks through 6 years of age.
3. Use of brand names is not meant to preclude the use of other comparable US licensed vaccines.

# Recommended Schedule and Intervals, III

Table 2: Children and Adolescents

Age	Schedule <sup>1, 6</sup>
Children (1 through 10 years)	0, 1, and 6 months <sup>2</sup>
	0, 2, and 4 months <sup>2</sup>
	0, 1, 2, and 12 months <sup>2,4</sup>
Adolescents (11 through 18 years)	0, 1, and 6 months <sup>2</sup>
	0, 1, and 4 months <sup>2</sup>
	0, 2, and 4 months <sup>2</sup>
	0, 12, and 24 months <sup>2</sup>
	0 and 4-6 months <sup>3</sup>
	0, 1, 2, and 12 months <sup>2,4</sup>
	0, 7 days, 21-30 days, 12 months <sup>5</sup>

## Table Notes

1. Children and adolescents may be vaccinated according to any of the schedules indicated, except as noted. Selection of a schedule should consider the need to optimize compliance with vaccination.
2. Pediatric/adolescent formulation.
3. A two-dose schedule of Recombivax-HB Adult Formulation is (10 micrograms) is licensed for adolescents aged 11 through 15 years. When scheduled to receive the second dose, adolescents aged > 15 years should be switched to a three-dose series, with doses 2 and 3 consisting of the pediatric formulation administered on an appropriate schedule.
4. A four-dose schedule of Engerix B® is licensed for all age groups.
5. Twinrix® can be administered to persons 18 years of age before travel or any other potential exposure on an accelerated schedule at 0, 7, and 21-30 days, followed by a dose at 12 months.
6. Use of brand names is not meant to preclude the use of other comparable US licensed vaccines.

# Recommended Schedule and Intervals, IV

## Interrupted schedules and minimum dosing intervals

- When the HepB vaccine schedule is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be administered as soon as possible, and the second and third doses should be separated by an interval of at least eight weeks. If only the third dose has been delayed, it should be administered as soon as possible.
- The **final** dose of vaccine must be administered at least eight weeks after the second dose and should follow the first dose by at least 16 weeks; the minimum interval between the first and second doses is four weeks. Inadequate doses of hepatitis B vaccine or doses received after a shorter-than-recommended dosing interval should be re-administered, using the correct dosage or schedule.

# Recommended Schedule and Intervals, V

## Interrupted schedules and minimum dosing intervals (continued)

- Vaccine doses administered  $\leq 4$  days before the minimum interval or age are considered valid. Because of the unique accelerated schedule for Twinrix®, the four-day guideline does not apply to the first three doses of this vaccine when administered on a 0 day, 7 day, 21-30 day, and 12 month schedule.
- In infants, administration of the final dose is not recommended before age 24 weeks (164 days).

# Recommended Schedule and Intervals, VI

## Revaccination

Revaccination (i.e., booster dose, challenge dose, or revaccination with a complete series) is not generally recommended for persons with a normal immune status who were vaccinated as infants, children, or adolescents. Revaccination when anti-HBs is  $<10$  mIU/mL is recommended for the following:

- Infants born to HBsAg-positive mothers
  - HBsAg-negative infants with anti-HBs  $<10$  mIU/mL should be re-vaccinated with a single dose of HepB vaccine and receive post vaccination serologic testing 1-2 months later. Infants whose anti-HBs remains  $<10$  mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine, followed by PVST 1-2 months after the final dose.
    - Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs  $<10$  mIU/mL may instead be revaccinated with a second, complete 3-dose series, followed by post vaccination serologic testing (PVST) performed 1-2 months after the final dose of vaccine.

# Recommended Schedule and Intervals, VII

## Revaccination (continued)

- Hemodialysis patients. For hemodialysis patients, the need for booster doses should be assessed by annual anti-HBs testing. A booster dose should be administered when anti-HBs levels decline to  $<10$  mIU/mL.
- Other immunocompromised persons. For other immunocompromised persons (e.g., HIV-infected persons, hematopoietic stem-cell transplant recipients, and persons receiving chemotherapy), the need for booster doses has not been determined. When anti-HBs levels decline to  $<10$  mIU/mL, annual anti-HBs testing and booster doses should be considered for persons with an ongoing risk for exposure.
- Persons with postvaccination serologic testing results that do not demonstrate protection. This includes children and adolescents through age 18 years who are chronic hemodialysis patients, HIV-infected, otherwise immunocompromised (e.g., hematopoietic stem-cell transplant recipients or persons receiving chemotherapy), or sex partners of HBsAg-positive persons. Persons in these groups found to have anti-HBs concentrations of  $<10$  mIU/mL after the primary vaccine series should be revaccinated.

# Dosage, Contraindications, Precautions

- **Recommended dosage**

Refer to product package inserts.

- **Contraindications and Precautions**

Contraindications and Precautions can be found in the package inserts available at

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM093833>

## Statement Regarding Update Based on Published Documents

[If an ACIP recommendation regarding Hepatitis B vaccination is published within 12 months following this resolution, the relevant language above (except in the eligible groups sections) will be replaced with the language in the recommendation and incorporated by reference to the publication URL.]